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24 NOV 2003

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1. Your reference

SJW/58327

2. Patent application number
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0327274.7

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

RETRACTOTOP LIMITED
Suite 102
Mercedes Build.
Corniche Road
P O Box 44539
Abu Dhabi
United Arab Emirates

Patents ADP number *(if you know it)*

8759284001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

DENTAL DEVICE AND METHOD FOR ITS USE

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Lloyd Wise
Commonwealth House
1-19 New Oxford Street
London
WC1A 1LW

117001

Patents ADP number *(if you know it)*

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications *(and if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month/ year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month/ year)*

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b) there is an inventor who is not named as an applicant,

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Continuation sheets of this form	
Description	6
Claim(s)	1
Abstract	1
Drawing(s)	3

1 3 SN

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Priority documents	
Translation of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Lloyd Wise — Date 24 November 2003

12. Name and daytime telephone number of person to contact in the United Kingdom — Sheila J. Wallace Tel. 020 6571 6200

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DENTAL DEVICE AND METHOD FOR ITS USE

The present invention relates to a dental device and a method for its use, intended for the inhibition of bleeding during various dental surgery operations.

In the process of constructing a dental crown, bridge or porcelain laminate, the teeth have to be shaped, and impressions taken of the prepared tooth; using a variety of impression materials. It is always essential to control the small amount of bleeding that occurs in the surrounding gingivae, around the periphery of the prepared tooth. It is also essential to retract the gingivae to enable the impression material to take an accurate impression of the margins of the preparation.

The usual method of controlling bleeding and retracting tissue is by the use of retraction cords. These are fine cords impregnated with epinephrine, racemic adrenaline hydrochloride and noradrenalin (synthetic adrenalin or astringents such as ferric or aluminium chloride).

The cords must be laboriously packed around the gingival margin of each prepared tooth and gently compressed into the sulcus with a special gingival retraction cords packer. The procedure is often difficult and time consuming, but is essential for successful impression taking.

Therefore, there is a need to provide a means for applying a haemostatic agent quickly and accurately into the gingival sulcus to control bleeding and to retract tissue. The present invention achieves this by means of a sheath which carries a haemostatic agent and is adapted to fit over the tooth.

A known dental product comprises compressible cotton wool caps but these are not functional to reduce or prevent bleeding by application of a haemostatic agent.

A first aspect of the present invention provides a dental device comprising a sheath for fitting over a tooth, the sheath carrying a haemostatic gent in at least one region thereof.

A second aspect of the present invention provides a method of inhibiting or preventing gingival bleeding, the method comprising placing over a tooth, a device according to the first aspect of the present invention.

The present invention permits drying and isolation of the preparation from contaminating saliva and thus creates an environment for a more accurate impression, around the preparation margins.

The present invention can also be used following the removal of temporary crowns prior to cementing the permanent crowns, where its action will be similar i.e. controlling any bleeding, drying and isolating the tooth from the contaminating saliva, reducing the need for painful air-drying of the prepared tooth.

A dental device according to the first aspect of the present invention comprises a sheath for fitting over a tooth. This can be placed over a tooth prior to preparation or after preparation. Preferably, this sheath comprises a generally cylindrical body having a first end and a second end, at least one of the first and second ends presenting a circumferential margin carrying at least par of the haemostatic agent.

The term "generally cylindrical" is not confined to generally cylindrical shapes having an axis of symmetry or indeed, to a perfect cylinder having a circular cross-section. The cross-section or shape may be regular or irregular. Possible regular shapes include oval or elliptical or square or rectangular shapes in cross-section, or indeed any polygonal shape, especially a generally polygonal profile having rounded corners. The shape could also be adapted to correspond to that of a given kind of tooth.

As used herein, the term "haemostatic agent" covers any substance or combination of substances which slow or prevent the flow of blood by any mechanism, be it clotting, vasoconstriction or any other mode of action. Suitable haemostatic agents include epinephrine, and astringents such as ferric chloride or, ferric sulphates, aluminium chloride, aluminium sulphate and any mixtures of the foregoing.

The haemostatic agent is carried in at least one region of the sheath. In this context, "carrying" can refer to impregnation or coating of the relevant region or regions, or

both. The haemostatic agent may be applied to the relevant region by any suitable means, such as dissolved in a suitable solvent, followed by drying or applied as a comminuted solid, e.g. by means of an orally compatible adhesive substance.

In preferred embodiments of the device according to the present invention, the at least one end carrying at least part of the haemostatic agent is open to a cavity and the other end of the device is closed. Preferably, such a cavity progressively narrows from the open end towards the closed end. It is also preferred for the closed end to be constructed so as to yield upon application of pressure, for example by being by virtue of the body of the device comprising or being plugged with cotton wool or any other resilient substance and/or being provided with slots or other means to allow the closed end to splay upon application of pressure.

Preferably also, the walls of the sheath are stiffened, but most preferably still retain some flexibility. This may be achieved by a construction utilising cellulose or other polymeric material or sheathing with paper or other non woven web. In general, the body of the device may be made of one or more suitable substances such as cotton wool, a cellulose, thin blotting paper, any suitable plastics material, including polythene (low density, medium density or high density), Visqueen™, synthetic or natural rubbers, including silicone rubbers, other silicones, papers, cardboards, fibreboards, metals such as soft aluminium or soft copper and wood as well as any laminate or composite or other combination of any two or more of the foregoing. The stiffening should not be too rigid, otherwise the occlusal pressure on the upper end could damage the delicate peripheral gingivae around the tooth.

A preferred class of embodiments comprises a resilient body such as of cotton wool, preferably with a cavity such as described above and a wall surrounding the body, eg of a stiffening material such as mentioned above.

It is convenient to provide a set of devices according to the present invention, at least of two of the devices in the set being of different sizes relative to each other, adapted for fitting over different sizes of teeth, e.g. large molars, small molars, pre-molars and incisors/laterals. It is also convenient for each such different size to be colour-coded for ease of recognition.

Devices according to the present invention may be used in any one of a variety of dental surgery operations, such as crowns or bridge work, implants, laminates and even routine conservative procedures where bleeding control is required.

The present invention will now be explained in more detail by reference to the following description of preferred embodiments and with reference to the accompanying drawings in which current –

Figure 1 shows a side elevation of the device according to the present invention prior to use;

Figure 2 shows the device of Figure 1 when subjected to pressure;

Figure 3 shows a device according to the present invention in cross-section; and

Figures 4A – 4E sequentially depict the stages of tooth preparation and treatment utilising a dental device according to the present invention.

Figures 1 to 3 show a device1 according to the present invention. This device 1 is essentially a sheath provided with a cylindrical wall 3 and presents an upper end 5 and a lower end 7. Figure 1 shows the device in side elevation before use and Figure 2 shows the same device in side elevation when the upper end 5 is subjected to pressure during use as will be described further herein below with reference to Figures 4A-4E.

The cylindrical wall comprises an absorbent blotting paper tube 9. The upper end 5 is provided with circumferential slots 11. 13 etc running parallel to the cylindrical axis. As shown in Figure 1, before use, these slots are substantially closed in the before-use configuration (Fig. 1) but when subject to pressure from above, on the upper surface 5, during use and as denoted by arrows 17, 19 etc, cause the segments 21, 23 between the slots, to splay apart so that the rim 25 at the upper end 5 is pushed outwardly (Fig. 2) so as to have, effectively, a wider diameter than that of the body of the cylindrical wall 3.

The lower circumferential margin 27 at the lower end 7 is impregnated in a region 29 around the lower circumference, with a haemostatic agent 31. In this particular

embodiment, this region 29 is impregnated with raecemic epinephrine hydrochloride as a concentration of 0.85mg/inch (per 25.5mm). The height of the impregnated region 29 from the lower end 7 is approximately 2mm. Other non-limiting possible haemostatic agents are mentioned elsewhere in this specification but for patients with heart conditions, it would be appropriate to replace the epinephrine by, for example, a 25% aluminium chloride or 20% ferric sulphate solution.

Referring also to Figure 3, which shows a cross-section through the device of Figures 1 and 2, the device inside the wall 3 contains a compressed cotton wool core 33 the upper end of which protrudes slightly in a region 35 above the rim of the upper end 5 of the device. The core 33 has formed therein, an opening 37 which is open to the air at the lower end 7. This opening 37 leads into a substantially conical cavity 39 which tapers in axial cross-section to a rounded apex 41 within the body of the device. The pitch of tapering denoted as angle θ is selected according to the particular size of device.

Use of the device1 in an operation of dental surgery such as fitting of a crown. These figures show an upper row of teeth 45, comprising a target tooth 47, depicted before treatment in Figure 4A.

As shown in Figure 4B, the target tooth 47 is first shaped (reduced in size) ready for offering-up of a dental crown (not shown).

Next, as shown in Figure 4C, the device 1 of an overall size chosen according to the target tooth 47 in question, is placed over that tooth so that the upper end 5, at which slots 13,15 etc are dispersed, points downwardly whilst the lower end 7, and in particular the rim 27 comes into contact with the gingival sulcus 49 of the gum 51. The haemostatic agent thereby prevents or inhibits bleeding.

As shown in Figure 4D, contact between the rim 27 and the gingival sulcus is enhanced upon application of bite when the lower row of teeth 53 is brought together with the upper row 45 and the pressure resulting thereby splays the finger sections 21,23 etc defined by the slots 13, 15 etc.

After sufficient contact time, to allow sufficient application of haemostatic agent to the wound, the device 1 is removed to leave the prepared target tooth 47, bleeding having effect been slowed or stopped.

Finally, a suitable crown is applied by means of conventional cement over the clean dry and prepared tooth.

The embodiment described above is given by way of example only and modifications of this embodiment, as well as other embodiments, all within the scope of the present invention, for example as defined by the appended, will now become apparent to persons skilled in the art.

CLAIMS:

1. A dental device comprising a sheath for fitting over a tooth, the sheath carrying a haemostatic agent in at least one region thereof.

2. A dental device according to claim 1, wherein the sheath comprises a generally cylindrical body having at least a first end and a second end, at least one of said first and second ends presenting a circumferential margin carrying at least part of the haemostatic agent.

3. A dental device according to claim 2, wherein the at least one end carrying at least part of the haemostatic agent is open to a cavity and the other end is closed.

4. A dental device according to claim 3, wherein the cavity progressively narrows from its open end towards the closed end.

5. A dental device according to claim 3 or claim 4, wherein said closed end is constructed to yield upon application of pressure.

6. A dental device according to any of claims 2 to 5, wherein the generally cylindrical body comprises a wall between said first and second ends at least part of the cylindrical wall being stiffened.

7. A set of dental devices according to any preceding claim, the devices in the set being of different sizes.

8. A set according to claim 7, wherein the devices being colour coded to denote their respective sizes.

9. A method of inhibiting or preventing gingival bleeding, the method comprising placing over a tooth, a device according to any of claims 1-7.

ABSTRACT

DENTAL DEVICE AND METHOD FOR ITS USE

A method and device for dental surgery in which a sheath is fitted over a tooth. The sheath carries a haemostatic agent.

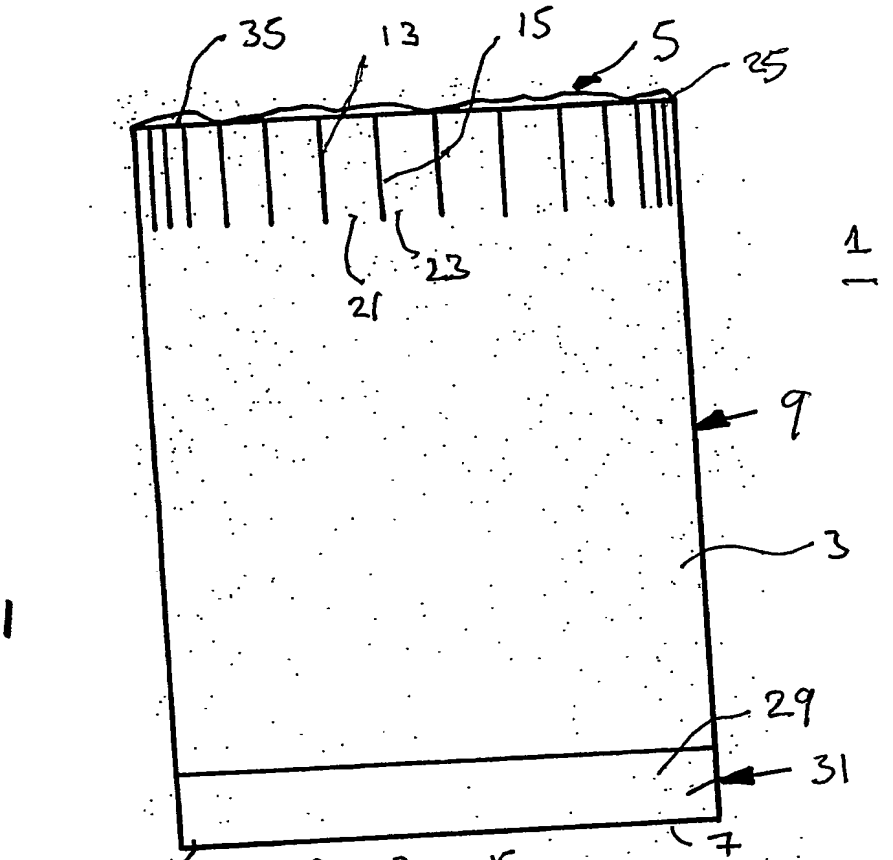
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FIG 1

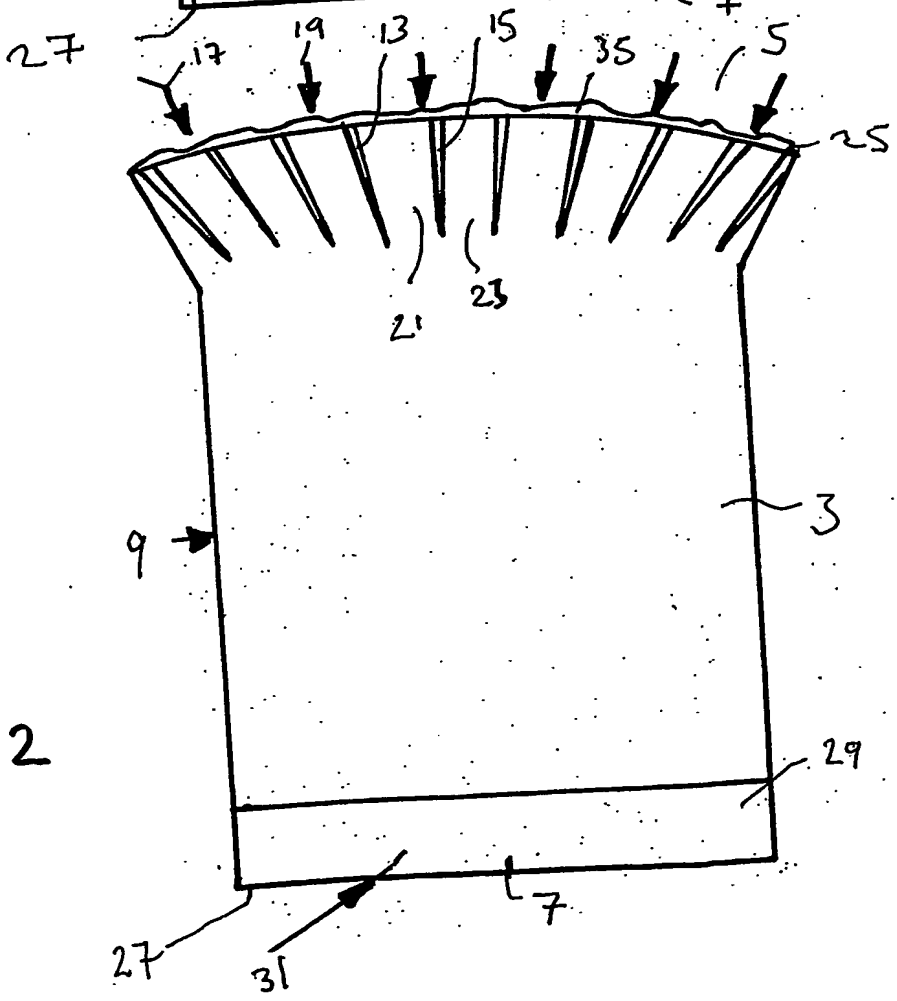
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FIG 2

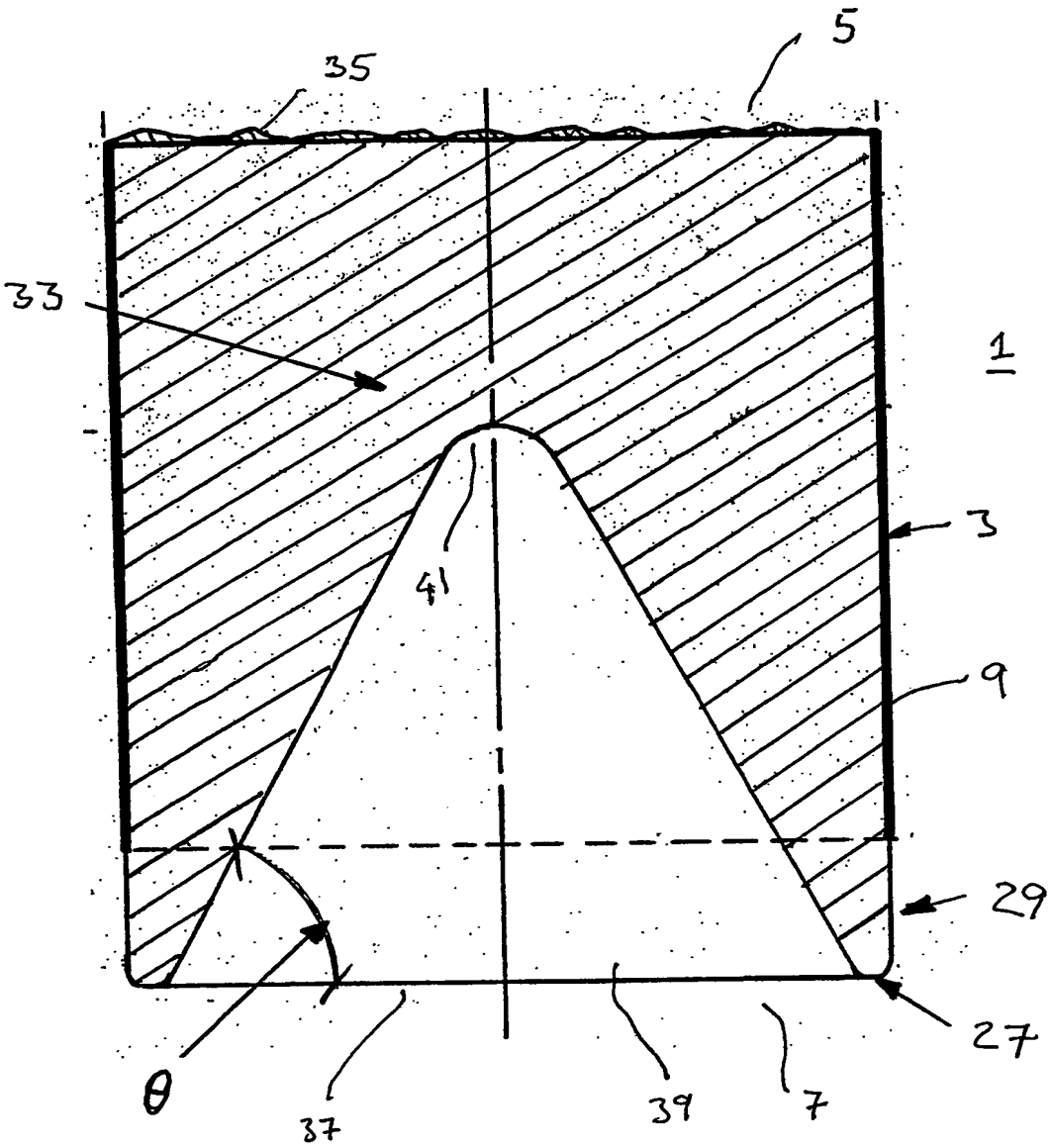

FIG 3

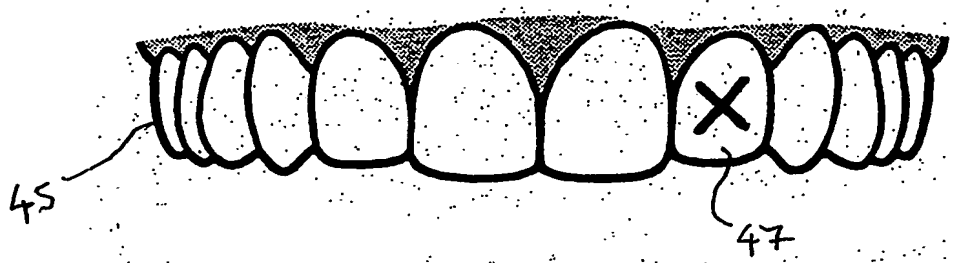

FIG 4A

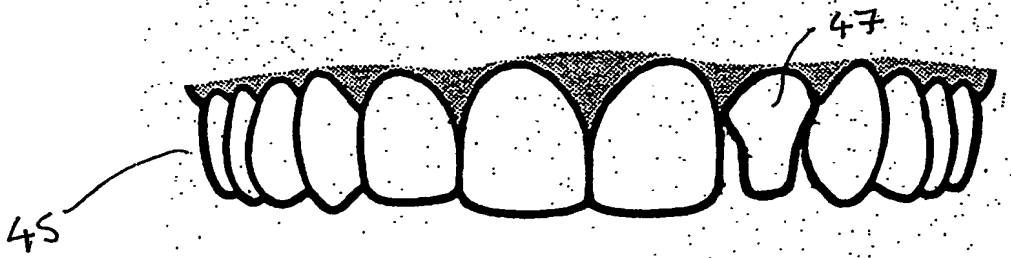

FIG 4B

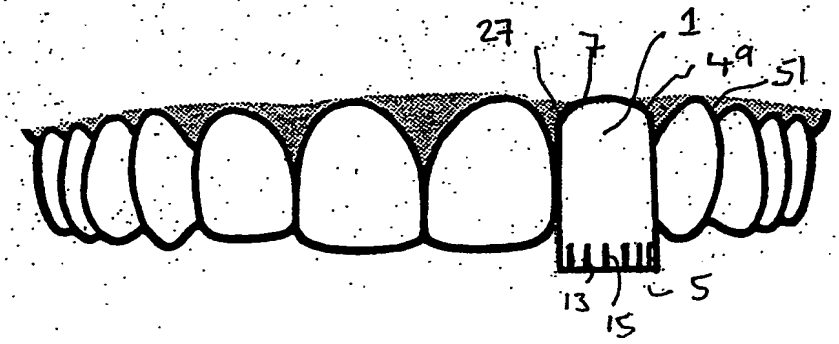

FIG 4C

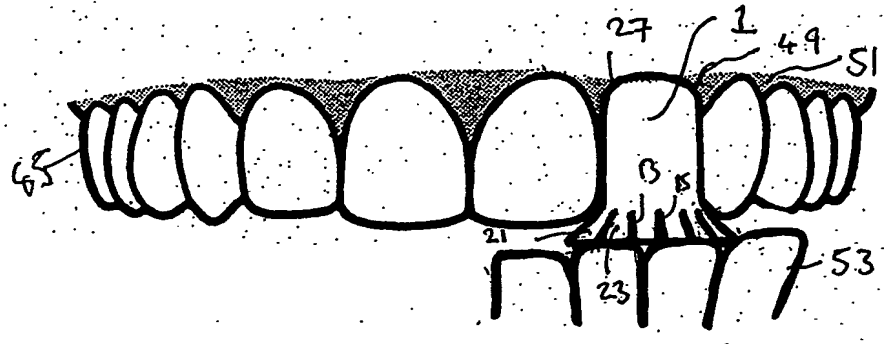

FIG 4D

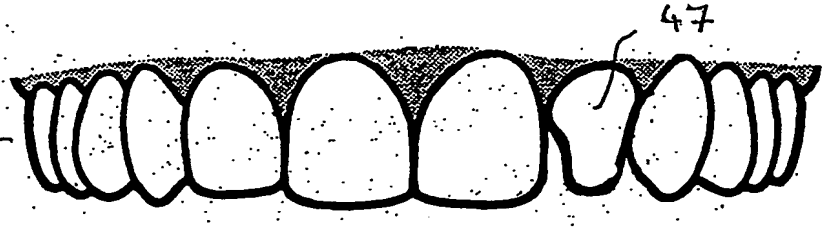

FIG 4E